DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 6/15/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered because references BA, BB and BC in the information disclosure statement filed 6/15/06 were not provided.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Crooke et al. (7,339,051, issued March 4, 2008).

Crooke et al. disclose oligomeric compounds which target a nucleic acid molecule encoding SARS virus (see column 8, lines 36-40) and kits comprising the compounds (see column 9, lines 5-6).

As indicated in the nucleic acid search report, SEQ ID NO: 6655 is identical with SEQ ID NO: 3 as recited in the instant claim and SEQ ID NO: 4612 is identical with SEQ ID NO: 6 as recited in the instant claim (see the attached nucleic acid report).

Thus the teachings of Crooke et al. anticipate the limitations of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2, 7, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooke et al. (7,339,051, issued March 4, 2008) in view of Buck et al. (BioTcheniques, 1999, Vol. 27 (3), pg. 528-536).

Crooke et al. disclose oligomeric compounds which target a nucleic acid molecule encoding SARS virus (see column 8, lines 36-40), a method for identifying a disease state by identifying the presence of a SARS virus in a sample using at least a one primer (see column9, lines 1-4) and kits comprising the compounds (see column 9, lines 5-6). Real time quantitative PCR analysis of SARS virus mRNA levels is performed by polymerase chain reaction in which a pair of primers, probes and reverse transcriptase is used (see columns 61-62, example 13). A probe which is specific for SARS is used for hybridization (see column 63, lines 16-20). Crooke et al. also disclose several fragments and complete genome sequences of SARS variants which are available in the public databases (see column 64, lines 21-22) and can be used for designing compound to target different structural regions or variants or motif of SARS (see column 64, table 2). SEQ ID NOs: 29738-29743, 29748, 29802, 29803, 29807, 29818-29820 of Crook et al. comprises SEQ IDNOs: 3, 4, 6, 7, 9 and 10 as recited in instant claims (see the attached nucleic acid search report). SEQ ID NO: 4717 is identical to SEQ ID NO: 11 used as a probe as recited in claim 8 (see the attached sequence search report).

Buck et al. disclose strategies to select a primer from a known nucleic acid sequence and all of the primers yielded data of extremely high quality (see pg. 535, column 2 last paragraph).

One of ordinary skill in the art would have been motivated to select SEQ ID NO: 3-4, 6-7 and 9-10 as primers for detecting the presence of SARS coronavirus nucleic acid sample because as indicated by Crooke et al. several fragments and complete genome sequences of SARS

variants are available in the public databases (see column 64, lines 21-22) and can be used for designing compound to target different structural regions or variants or motif of SARS (see column 64, table 2) and Buck et al. disclose strategies to select a primer from a known nucleic acid sequence and all of the primers yielded data of extremely high quality (see pg. 535, column 2 last paragraph). It would have been prima facie obvious to apply SEQ ID NO: 3-4, 6-7 and 9-10 as primers in detecting SARS coronavirus with reasonable expectations of success.

None of the references above indicates that one of the primers is specific for a NSP1 region of a SARS coronavirus.

Since the specification disclose that NSP1 is part of SARS coronavirus (see [0025] and [0028]) and the location of these primers at position 6652-7003 of a NSP1 region (see [0038]), Crooke et al. also disclose several fragments and complete genome sequences of SARS variants which are available in the public databases (see column 64, lines 21-22) and can be used for designing compounds to target different structural regions or variants or motif of SARS (see column 64, table 2), the primers designed from the fragments and complete genome sequences of SARS variants would have the function which is specific for a NSP1 region used in detecting SARS coronavirus with reasonable expectations of success. It would have been prima facie obvious to apply SEQ ID NOs: 3-4, 6-7 and 9-11 as primers and probes in detecting SARS coronavirus with reasonable expectations of success.

6. Claims 3-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooke et al. (7,339,051, issued March 4, 2008) as applied to claims 1-2 and 7 above, and further in view of Beckmann et al. (6,232063, issued May 15, 2001) and Gillim-Ross et al. (7,129,042, issued Oct. 31, 2006).

Crooke et al. do not disclose that SEQ ID NO: 3-4, 6-7 and 9-10 are paired and certain length of the amplification products is expected.

Crooke et al. do disclose that RT-PCR reaction is performed with a forward primer and a reverse primer (see column 62, lines 6-15).

Gillim-ross et al. disclose the benefit of using two primers which are complementary to their respective strands of the double stranded target sequence (see column 38, lines 42-43 and lines 48-53).

One of ordinary skill in the art would have been motivated to apply a primer pair in an amplification reaction because by doing so a high concentration of an amplified segment of a desired target sequence is obtained (see column 38, lines 50-53). It would have been prima facie obvious to apply a primer pair in the detection of SARS coronavirus.

Crooke et al. do not disclose an expected nucleic acid amplification product with a specific size which is detected.

Beckmann et al. disclose a method for detecting the homozygous or heterozygous state mutations in which analyzing the size of the amplified fragments (such as chromatography) can be considered as an equivalent means in the method of the invention (see column 2, lines 12-19).

In addition, the phrase "expected" recited in the claims is interpreted as that this specific size of the amplification might not exactly happen.

One of ordinary skill in the art would have been motivated to detect a specific size of an amplified product for detecting SARS cononavirus nucleic acid in a sample because Beckmann et al. disclose that it is rapid and avoids experimentation using radio-elements (see column 6,

lines 28-32). It would have been prima facie obvious to expect a specific size of an amplified product which is detected.

7. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooke et al. (7,339,051, issued March 4, 2008) in view of Buck et al. (BioTcheniques, 1999, Vol. 27 (3), pg. 528-536) and Beckmann et al. (6,232,063, issued May 15, 2001).

As disclosed in the specification, three sets of primer pairs are identified from NSP1 proteinase region located at position 2694-9959 (see fig.1). A first primer pair, SEQ ID NOs: 3-4 is for amplifying the portion of the SARS coronavirus genome from nucleotide 6652-7003 (see pg. 4, [0044]-[0045]). A second primer pair, SEQ ID NOs: 6 and 7 is for amplifying the portion of the SARS coronavirus genome from nucleotide 4600 to nucleotide 4765 (see pg. 5, [0054]). A third primer pair, SEQ ID NOs: 9 and 10 is for amplifying the portion of the SARS coronavirus genome from nucleotide 4689-4765 (see fig. 1).

The teachings of Crook et al. are set forth in section 5 above. Specifically, Crook et al. disclose that SEQ ID NOs: 29738-29743, 29748, 29802, 29803, 29807, 29818-29820 comprises SEQ IDNOs: 3, 4 6, 7, 9 and 10 as recited in instant claims (see the attached nucleic acid search report). SEQ ID NO: 4717 is identical to SEQ ID NO: 11 used as a probe as recited in claim 8 (see the attached sequence search report).

Buck et al. disclose strategies to select a primer from a known nucleic acid sequence and all of the primers yielded data of extremely high quality (see pg. 535, column 2 last paragraph).

The primers or probes designed from the fragments as disclosed by Crook et al. would function in amplifying the region of the SARS coronavirus genome from nucleotide 6652 to

nucleotide 7003, and from 4609 to nucleotide 4765 and to detect an amplified probe via hybridization.

One of ordinary skill in the art would have been motivated to select a primer or probe which is designed from the fragments disclosed by Crook et al. because Buck et al. disclose that Buck et al. disclose strategies to select a primer from a known nucleic acid sequence and all of the primers yielded data of extremely high quality (see pg. 535, column 2 last paragraph). It would have be prima facie obvious to apply primers and probes for amplifying from nucleotide 6652 to nucleotide 7003 and nucleotide 4609 to nucleotide 4765 in detecting SARS coronavirus with a reasonable expectations of success.

None of the references cited above disclose determining the length of the amplification product in nucleotides as recited in instant claims 10 and 13.

Beckmann et al. disclose a method for detecting the homozygous or heterozygous state mutations in which analyzing the size of the amplified fragments (such as chromatography) can be considered as an equivalent means in the method of the invention (see column 2, lines 12-19).

One of ordinary skill in the art would have been motivated to determine the length of the amplified product for detecting SARS cononavirus nucleic acid in a sample because Beckmann et al. disclose that it is rapid and avoids experimentation using radio-elements (see column 6, lines 28-32). It would have been prima facie obvious to apply a specific size of an amplified product which is detected.

Summary

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Joyce Tung/
Examiner, Art Unit 1637
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